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By: \_\_\_\_\_  
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**PATENT: Mail Stop AF**

Customer No. 22,852

Attorney Docket No. 07579.0015-01000

**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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In re Application of:

Graham Edmund KELLY et al.

Application No.: 10/600,004

Filed: June 18, 2003

For: COMPOSITIONS FOR  
CARDIOVASCULAR AND BONE  
TREATMENT USING  
FORMONONETIN AND OTHER  
ISOFLAVONES

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)  
) Group Art Unit: 1614  
)  
) Examiner: C. DELACROIX-MUIRHEID  
)  
)  
) Confirmation No.: 6037  
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OCT 13 2005

**Mail Stop AF**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Sir:

Applicants request a pre-appeal brief review of the Final Office Action dated April 13, 2005 ("Final Office Action"). This Request is being filed concurrently with a Notice of Appeal.

**I. Requirements For Submitting a Pre-Appeal Brief Request for Review**

Applicants may request a pre-appeal brief review of rejections set forth in an Office Action if (1) the application has been at least twice rejected; (2) Applicants concurrently file the Request with a Notice of Appeal and prior to an Appeal Brief; and (3) Applicants submit a Pre-Appeal Brief Request for Review that is five (5) or less pages in length and sets forth legal or factual deficiencies in the rejections. See Official Gazette Notice, July 12, 2005.

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Applicants have met each of these requirements and therefore request review of the Examiner's rejections in the Final Office Action for the reasons set forth below. The arguments raised below are not a comprehensive set of Applicants' objections to the Final Office Action, and Applicants reserve the right to raise additional arguments on appeal, including arguments that could have been raised here.

**II. The Office Committed Clear Errors in Maintaining that Kelly '703 is Prior Art**

The Office clearly erred in maintaining that Rule 132 declarations can only be submitted where the subject matter is "disclosed but not claimed" in the pending application and more specifically, in finding that Applicants' prior declaration did not remove Kelly '703 as prior art. Office Action at page 3. The Office cited M.P.E.P. § 715.01(a) and M.P.E.P. § 716.10 as support for its position. Applicants respectfully contend that the cited M.P.E.P. sections are incorrect as they do not reflect amendments to the rules made on September 20, 2000. 65 Fed. Reg. 57,024 (Sept. 20, 2000) (*See Exhibit A in Amendment After Final, filed October 12, 2005*).

While Section 1.132 was expressly amended in September 2000, it does not appear that M.P.E.P. Section 715.01(a) was ever amended to reflect the changes in Section 1.132. The first sentence of Section 715.01(a), in particular, reflects the language from the old version of Section 1.132, stating there are limitations on when a Rule 132 declaration can be used to overcome a rejection. M.P.E.P. § 715.01(a) at 700-243 ("When subject matter, disclosed but not claimed in a patent or application publication...."). However, it is clear that, based on the September 2000 amendment, and regardless of the incorrect, limiting language of Section 715.01(a), a Rule 132 declaration is entirely appropriate to address subject matter that is claimed in a patent or in an application. 65 Fed. Reg. 54,604, 54,640 (Sept. 8, 2000) (*See Exhibit B in Amendment After Final, filed October 12, 2005*). Indeed, the only limitation on submitting a Rule 132 declaration to overcome a prior art rejection is that the prior art not be the invention of another. *Id.*

Accordingly, Applicants respectfully suggest that the M.P.E.P. section upon which the Office relies is outdated and incorrect. Under Section 1.132, as amended, Applicants submitted proper declarations that effectively removed Kelly '703 as prior art.

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**III. The Office Did Not Establish a *Prima Facie* Case of Obviousness In Rejecting Claims**


The claims are rejected under 35 U.S.C. § 103(a) as unpatentable over Kelly '069 in view of Empie and Kelly '703. The Office had cited Kelly '703 as disclosing a method of treating osteoporosis by administering to a patient in need thereof a composition containing an effective amount (10:1 to 1:10) of formononetin and daidzein. However, as provided above, Kelly '703 should be removed as prior art. Neither of the other recited references teaches or suggests "high proportions of formononetin." Indeed, both references expressly teach away from this concept. (See Applicants Amendment and Response mailed October 12, 2005.) Accordingly, the Office did not establish a *prima facie* case of obviousness in rejecting the claims and clearly erred in maintaining the rejection.

**IV. Conclusion**

Because the Examiner's rejection of the pending claims includes legal deficiencies, Applicants are entitled to a pre-appeal brief review of the Final Office Action. And based on the foregoing arguments, Applicants request that the rejection of these claims be withdrawn and the claims allowed.

Respectfully submitted,

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